TITLE: Informed Consent Process Requirements

1.0 PURPOSE

This Standard Operating Procedure (SOP) sets forth the policies and procedures required by the VA Central IRB as part of the informed consent process. This includes the required elements of informed consent, the process of obtaining informed consent, documentation of informed consent, and requirements for requesting a waiver or alteration of the informed consent process and/or a waiver of documentation of informed consent.

2.0 REVISION HISTORY

Date of Initial Approval	July 29, 2008
Revision Dates	April 24, 2009 September 23, 2009 March 18, 2010

3.0 SCOPE

This SOP applies to all VA investigators and members of their project teams who submit projects involving the use of human participants to the VA Central IRB for review. It also pertains to VA Central IRB members and the VA Central IRB administrative support staff.

4.0 POLICY

4.1 It is the policy of the VA Central IRB that an investigator may not involve a human being as a participant or subject in non-exempt research the VA Central IRB oversees unless the investigator or the investigator's designee obtains the informed consent of the person or the person's legally authorized representative, unless the requirement for obtaining such consent is waived by the VA Central IRB.

4.1.1 If someone other than the investigator conducts the interview and obtains consent from a participant or the participant's legally authorized representative, the investigator needs to formally delegate this responsibility in writing, and the person so delegated must have appropriate qualifications and have received appropriate training to perform this activity.

4.1.2 All project personnel involved in the informed consent process must be knowledgeable about the research to be conducted and the process for obtaining informed consent. They must be able to answer questions about the project.

4.2 An investigator can seek consent only under circumstances that provide the prospective participant, or the participant's legally authorized representative, sufficient opportunity to consider whether or not to participate. The investigator must also

minimize the possibility of undue influence or coercion. If a participant's legally authorized representative provides surrogate consent, assent must be sought from the participant whenever possible.

4.3 The information given to the participant or the participant's representative must be in language understandable to the participant or the participant's representative.

4.4 No informed consent, whether oral or written, may include any exculpatory language through which the participant, or the participant's legally authorized representative, is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 It is the expectation of the VA Central IRB that investigators are responsible for:

6.1.1 Ensuring that informed consent is obtained from a participant or a participant's legally authorized representative prior to conducting any research activities with the subject in accordance with the requirements of this standard operating procedure and VA and other federal requirements.

6.1.2 Creating an informed consent document containing all required basic elements, as well as any additional elements as applicable, for the participant populations that will be enrolled and describing the type of research that will be conducted. The investigator will obtain approval of this document by the VA Central IRB prior to initiating any research activities or enrolling any participants.

6.1.3 Ensuring that such informed consent is appropriately documented.

6.1.4 Ensuring that all members of the investigator's project team who seek informed consent are appropriately qualified and trained to perform this function.

6.1.5 Maintaining documentation of informed consent in accordance with VA requirements, to include keeping a copy of the signed informed consent document in the research study file, as well as forwarding a copy for file in the subject's medical record if applicable.

6.1.6 Appropriately requesting a waiver when a consent procedure does not include, or which alters, some or all of the elements of informed consent set forth in this section.

6.1.7 Appropriately requesting a waiver of documentation of informed consent, when needed.

6.2 The VA Central IRB is responsible for evaluating investigator compliance with the policies and procedures on seeking informed consent or assent from participants.

6.2.1 The VA Central IRB will review the entire informed consent process, including the informed consent document, the processes by which informed consent is obtained from each participant, and how participants are recruited. The VA Central IRB will review the process with a focus on improving the participant's understanding and voluntary decision making. This will be done through a combination of review of Local Site Investigator Applications, local site Research Compliance Officer audit reports, other outside audit reports, and on-site visits by VA Central IRB personnel.

6.2.2 The VA Central IRB will also review requests from investigators to waive or alter the informed consent process.

6.3 The VA Central IRB Coordinators and the Administrator are responsible for ensuring that investigators are adequately informed of the VA Central IRB's requirements for submitting a project involving the use of human subjects to the VA Central IRB for review. This includes making available the applicable forms and checklists to aid investigators in ensuring their applications are complete and contain all necessary documentation required for the VA Central IRB to adequately review the investigator's proposed informed consent process, or a request for waiver or alteration of this process.

7.0 PROCEDURES

7.1 Informed Consent Required Elements. All investigators submitting projects to the VA Central IRB who plan to seek informed consent from participants or the participants' legally authorized representatives will submit a proposed informed consent document using the VA Central IRB template of the VA Form 10-1086, Research Consent Form (Attachment 1.) The following are the required elements that must be in **all** informed consent forms submitted to the VA Central IRB:

- The name of the project and the name of the Principal Investigator (PI).
- A statement that the project involves research and an explanation of the purposes of the research
- The expected duration of a participant's participation and the approximate number of participants to be involved in the project if known.
- A description of the procedures to be followed, identifying any procedures which are going to be performed solely for research purposes and/or any procedures that are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant to include any privacy risks that may result from the research.
- A description of the potential benefits to the participant or to others that may reasonably be expected from the research.

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- A statement describing the extent to which, if any, confidentiality of records identifying the participant will be maintained and that there is a possibility that other federal agencies such as the VHA Office of Research Oversight (ORO), the Office for Human Research Protections (OHRP), and the Government Accountability Office (GAO) may have access to the records. If an FDA-regulated test article is involved, there must be an additional statement indicating the FDA may choose to inspect research records that include the participant's medical records.
- For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available from the VA if injury occurs; what those treatments consist of; what the VA's authority is to provide such treatment; and where further information can be obtained. .
- An explanation of whom to contact with questions about the following: questions about the research; concerns, or complaints about the research; the research participant's rights: in the event of a research-related injury; and to verify that the project in question is a valid VA project. The contact's name and phone number for questions about the participant's rights and whom to contact to verify that the project is a valid VA project, must be someone knowledgeable but not affiliated with the specific research project. The VA Central IRB toll free number (877-254-3130) will be included.
- A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that a Veteran participant will not be required to pay for care received that is part of a VA research project. They will, however, be required to pay any co-payments they would ordinarily be required to pay for any nonresearch related VA medical care and/or services.

7.2 Additional Informed Consent Elements. One or more of the following additional elements of informed consent should also be included in the informed consent form **if appropriate or applicable**:

- A statement that the particular treatment or procedure may involve currently unforeseeable risks to the participant or to an embryo or fetus if the subject becomes pregnant.
- A statement advising potential participants that risks associated with "usual care" and not from the research should be reviewed with their health care providers.
- Any anticipated circumstances under which the participant's participation in the research may be terminated by the investigator without the subject's consent, such as noncompliance with the project procedures, if the investigator determines that termination is in the interest of the participant's safety or well-being, or if a data safety monitoring board determines the research must stop.

- Any additional costs to the participant that may result from participation in the research consistent with federal laws concerning the Veteran's eligibility for medical care and treatment, such as transportation and lost time from work.
- An explanation of the consequences of a participant's decision to withdraw from the research and the procedures for the orderly termination of participation by the participant.
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant to include the procedures for contacting the participants and for confirming their continued participation if applicable.
- If investigators believe that the human biologic specimens being collected in conjunction with the research could be part of or lead to the development of a commercially valuable product, a statement that participants will not be able to profit from any product or test developed as a result of using their sample.
- As appropriate, a statement regarding any payment the participant is to receive and how it will be made, to include a description of how payment will be prorated and calculated for participants who withdraw early.
- A clear statement concerning any conflict of interest by investigators involved with the project or the institution at which the research will be performed that has not been resolved or eliminated.
- If photographs or voice recordings are to be made and kept in the participant's medical record, a statement that an additional consent form (VA Form 10-3203, Consent for Use of Picture and/or Voice) must also be completed

7.3 Required Elements if Collecting Biological Specimens to be Banked.

7.3.1 For projects involving the collection of biological specimens that will be banked, the informed consent under which the specimens are collected will contain all of the above required elements, any of the additional elements as applicable, and it will also clearly state the following:

- The types of specimens that will be stored and the name and location of the biorepository/tissue bank where they will be stored.
- Whether the specimen will be used for future research to include provisions for allowing the participant the choice of how the specimen will be used, i.e., for any research, only research by the current PI, prohibit genetic analysis, etc.
- The length of time the specimen will be stored.
- When and under what conditions research results will be conveyed to the participant, the participant's family, or the participant's physician.
- Whether the participant will be re-contacted after the original project is completed.
- If the participant requests, the specimen will be destroyed and the data no longer used available for future research. The participant will be advised that data that has already been used in a project cannot be withdrawn.

7.3.2 All studies involving genetic analysis will contain the language, as suggested by OHRP, pertaining to the Genetic Information Non-Discrimination Act (GINA). Substantial sub-studies involving genetic research and analyses will require a separate consent form from the rest of the main study. If there is to be a separate genetic substudy, this should be stated in the main study informed consent document and reference made to the additional form and consent process for the study.

7.3.3 If tissue is going to be collected as part of Cooperative Studies Program (CSP) projects solely for banking in the CSP Tissue Biorepository a separate VA Central IRB-approved informed consent document as required by the VA Genomic Medicine Program must be completed by the participant.

7.4 Language and Readability. The language used in the informed consent form will be simple and understandable to all potential subjects. Any scientific or technical terms used must be adequately explained using common or lay terminology.

7.4.1 If a potential subject population reads or speaks a language other than English, the VA Central IRB will determine if a translated copy of the consent form in the subjects' language must be developed and submitted for review or if any other accommodations should be made, such as having a translator present during the consent process.

7.4.2 The readability of the informed consent form must be measured using a software program, such as the Flesch-Kincaid Grade Level Scoring System that is available in Microsoft Word, or any other system available. The score should be in the range of an 8th grade reading level. Higher reading grade levels will be considered based on the participant population being targeted. This score will be provided to the VA Central IRB on the VA Form 108, Principal Investigator/Study Chair New Project Application. If the Flesch-Kincaid system is not used, the investigator will indicate what system was used and provide an explanation of the scoring system, along with the score. If the investigator does not have a means of providing readability score, the VA Central IRB administrative staff will perform the readability testing using the Flesch-Kincaid system.

7.5 Informed Consent Template. The written informed consent will be documented using the VA Form 10-1086 in the VA Central IRB format. The VA Central IRB does not allow use of a short form. The version of the VA Form 10-1086 used for a study will be the most current version as approved by the VA Central IRB. Once approved, the date of approval will be documented by the VA Central IRB Coordinator by placing a date stamp on each page of the consent form. The VA Central IRB will keep a copy of each approved version of the consent form in the project file.

7.6 Documenting the Informed Consent Process.

7.6.1 Upon completion of the interview, the informed consent form will be signed and dated by all of the following individuals unless one or more of these requirements is waived by the VA Central IRB:

- The participant or the participant's legally authorized representative
- A witness whose sole role is to witness the participant's or the participant's legally authorized representative's signature on the consent form. If required by the VA Central IRB or a sponsor, the witness will witness the entire informed consent process. When witnessing the entire consent process, the witness is attesting that the information was apparently understood by the participant and that informed consent was given freely by the participant or LAR as applicable. The requirement for obtaining a witness signature cannot be waived by the VA Central IRB when documented informed consent is being obtained.
- The person obtaining the informed consent.

7.6.2 The original signed consent form will be kept in the participant's project case history and a copy provided to the participant or the participant's legally authorized representative.

7.6.3 If the participant is a VA patient with a medical record and the research intervention is taking place at a VA facility as part of a documented encounter that will be filed in the VA patient's medical record, a copy of the signed informed consent document is to be filed in the record and the following actions must also occur:

7.6.3.1 A progress note documenting the informed consent process will be placed in the participant's medical record at the time consent is given and at the time the participant begins any project interventions. Consent and entry notes can be combined if they both occur at the same time. At a minimum, the progress consent and/or beginning intervention note(s) will include all of the following:

- The name of the project
- The name of the person obtaining the participant's consent
- A statement that the participant or the participant's legally authorized representative was capable of understanding the consent process
- A statement that the project was explained to the participant
- A statement that the participant was given the opportunity to ask questions
- The date written or oral consent was obtained.

7.6.3.2 The medical records on participants who have interventions as part of a documented patient encounter must contain information on all research and experimental interventions including potential risks, indications, and applicable progress notes. Another progress note will be documented when the participant's participation is terminated.

7.6.4 If informed consent is being obtained from the participant's legally authorized representative (LAR), the LAR must be informed of their role and obligation to protect the participant and to act in what the LAR determines to be the participant's best interest.

7.7 Requesting a Waiver or Alteration of the Informed Consent Process.

7.7.1 If the research does not utilize an FDA-regulated device or product, investigators may request a waiver or an alteration of the process of informed consent. In order to do this, they will complete VA Central IRB Form 112a, Request for Waiver or Alteration of the Informed Consent Process (Attachment 2) as part of the Principal Investigator/Study Chair New Project Application process.

7.7.2 Investigators should only complete the VA Central IRB Form 112a if their research meets one of the following criteria:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine one or more of the following:
  - Public benefit or service programs
  - Procedures for obtaining benefits or services under those programs
  - Possible changes in or alternatives to those programs or procedures
  - Possible changes in methods or levels of payment for benefits or services under those programs

OR

- The research meets all of the following criteria:
  - The research involves no more than minimal tangible or intangible risk to the participants
  - The waiver or alteration will not adversely affect the rights and welfare of the participants
  - The research could not be carried out without the waiver or alteration
  - Whenever appropriate, the participants are to be provided with additional pertinent information after participation

7.7.3 Even if a waiver or alteration of the informed consent process is granted, the VA Central IRB may still require other conditions of the investigator, such as additional information security measures.

7.8 Requesting a Waiver for Documentation of Informed Consent.

7.8.1 Investigators may request a waiver of the requirement to obtain a signed informed consent document. To do this, they must complete VA Central IRB Form 112b, Request for Waiver of Documentation of Informed Consent (Attachment 3), and submit it as part of the Principal Investigator/Study Chair New Application Process.

7.8.2 Investigators should not request such a waiver unless their research meets **one** of the following criteria:

- The research involves no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

OR

- That the only record linking the participant and the research would be the consent document and the principal risk to the participant would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the subject with the research and the participant's wishes will govern. If the participant wants to be linked with the research, the participant will be offered an informed consent form for signature.

7.8.4 Even if a waiver of the of the requirement to obtain a signed consent form is granted, the VA Central IRB may still require other conditions of the investigator, such as providing subjects with an information sheet or other documentation about the research.

7.9 Requesting a Waiver of Informed Consent for Recruitment Purposes Only.

7.9.1 If an investigator intends to obtain identifiable private information for use in recruitment of participants, a request for waiver of both informed consent and waiver of the requirement for HIPAA authorization under the HIPAA Privacy rule must be submitted. Please see VA Central IRB SOP 124, VA Central IRB HIPAA Responsibilities.

7.9.2 The only exception to the requirement for requesting a waiver of the informed consent requirement for recruitment purposes only is if a participant previously gave permission to be contacted for future research purposes, such as if the identifiable information was obtained from a registry set up to promote future research. In this case, the VA Central IRB may want confirmation from the registry or will want to see a sample consent form indicating this permission was solicited and granted.

7.10 Review of Informed Consent Process by the VA Central IRB.

7.10.1 When reviewing the informed consent process as part of the approval process for a study the VA Central IRB must ensure the following:

- Sufficient opportunity is provided for the subject to consider whether or not to participate in a project and to read the informed consent document before it is signed and dated
- The possibility for coercion or undue influence is minimized
- Surrogate consent is only accepted if the potential participant is incompetent, a minor, or has an impaired decision-making capacity as determined and documented in the person's medical record in a signed and dated progress note

- Information is provided in language understandable to the subject
- The process does not include any exculpatory language
- The informed consent document contains all basic required elements, as well as any additional elements required depending on the study.

7.10.2 When reviewing requests for waiver or alteration of the informed consent process or when reviewing requests for waiver of the requirement for documentation of informed consent, the VA Central IRB must ensure that all the applicable approval criteria for the requested waiver or alteration are met for the specific study. Upon approval of a requested waiver, the VA Central IRB Co-Chair signs the applicable VA Central IRB Form 112a or 112b. The review of the approval criteria will also be documented in the meeting minutes and referenced in the letter to the investigator.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.3 45 CFR 46, Department of Health and Human Services, Protection of Human Subjects

8.4 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

8.5 VHA Directive 2000-043, Banking of Human Research Subjects' Specimens and CRADO Memorandum dated March 28, 2001, "VHA Directive 2000-043: Banking of Human Research Subjects' Specimens

8.6 VHA Handbook 1605.01, Privacy and Release of Information

8.7 VHA Handbook 1907.01, Health Information Management and Health Records

8.9 Interim Guidance on Protecting the Rights and Welfare of Human Subjects in Research Involving "Usual Care."

3 Attachments
1. VA Form 10-1086 as modified by the VA Central IRB, Investigator Guidelines and Template for Preparing an Informed Consent Form
2. VA Central IRB Form 112a, Request for Waiver or Alteration of the Informed Consent Process
3. VA Central IRB Form 112b, Request for Waiver of Documentation of Informed Consent

I have read and approved the content of this SOP.

K. Lynn Cates, MD
Director, PRIDE

Date: 4/2/2010

Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

VA CENTRAL IRB INFORMED CONSENT TEMPLATE

INTRODUCTION

Include the following verbatim:

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve, to include any potential risks to you as well as any potential benefits you may receive

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

Briefly inform the participant of the following. Include at a minimum all the items listed below that are applicable to your study. These bullets should be addressed in separate paragraphs with sub-headings as needed to maintain organizational clarity.

- *Why the research is being done. State what is being studied, e.g.,* With this research we hope to learn.... *State what the study is designed to discover or establish.*
- *Why human participants are being asked to take part. (If there is a condition or circumstance that makes the person eligible for the study, include this here.)*
- *Why current therapies are not satisfactory and/or why an alternate treatment approach will be used.*
- *If a drug or device used in the project has or has not been approved by the Food and Drug Administration for the specific use being evaluated in the project.*

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- *The number of participants who will be enrolled in the project locally and nationwide (if multisite).*
- *Who will be conducting the study and who is sponsoring it.*

DURATION OF THE RESEARCH

Explain the expected duration of the entire study. The participants must also be informed of their individual time commitment for participation in the total study, e.g., This research study is expected to take approximately x days, weeks, months; this is a two-year study; etc.

In the STUDY PROCEDURES section that follows, explain the participant's time involved for each procedure or interaction.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen: *The investigator must provide a detailed description of the following as applicable.*

- *A chronological explanation of the procedures that will be performed, distinguishing which procedures are experimental (to include the use of investigational drugs and devices) which are considered standard treatment, and which are being done solely for the purposes of the research.*
- *For research involving randomization of participants into different study arms, specify the randomization process, explaining it in lay language.*
- *A full explanation of all responsibilities and expectations of the participant. Include applicable points from the list that follows and/or add your own per study requirements:*
    - Take the study drug as instructed. (If device, explain what is required for study compliance).
    - Keep your study appointments. If it is necessary to miss an appointment, please contact the investigator or research study staff to reschedule as soon as you know you will miss the appointment.
    - Tell the investigator or research study staff if you believe you might be pregnant or might have gotten your partner pregnant.

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

- Keep the study drug in a safe place, away from children and for your use only.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without approval from the investigators may invalidate the results of this research, as well as that of the other studies

- *A summary of the different people with whom the participant will interact.*
- *An explanation of when and where the research will be done.*
- *How often the procedures will be performed and how long each procedure will take.*
- *Type and frequency of safety monitoring during and after the study.*
- *If applicable, include information regarding pregnancy testing for women of childbearing potential and indicate the frequency of pregnancy testing.*
- *If the study includes surveys or questionnaires, include a statement that the participant is free to skip any questions that he/she would prefer not to answer.*

POSSIBLE RISKS OR DISCOMFORTS

Suggested wording that can be modified based on the type of research you are proposing to conduct: Any procedure has possible risks and discomforts. The procedures in this study may cause all, some or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unanticipated) risks also may occur.

- *Identify each intervention with a subheading and then describe any reasonable foreseeable risks, discomforts, and inconveniences, and how these will be managed. Include the probability of the risks, especially those that are likely and those that are rare but serious.*

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

- *In addition to physiological risks/discomforts, describe any psychological, social, legal, or financial risks that might result from participating in the research, to include risks inherent in genetic analysis and tissue banking if applicable.*
- *If there are any significant risks to participation that might cause the researcher to withdraw the participant or terminate the study, these should be described.*
- *Give measures which will be employed to minimize the described risks, discomforts, and inconveniences.*

For studies involving possible reproductive risks, please include a section that includes the following:

- *State any known risks in pregnancy, either to mother or child.*
- *State that there may be unforeseeable (unanticipated) risks to the participant (or to the embryo or fetus) if the participant is pregnant or becomes pregnant during the study.*
- *List the acceptable methods of birth control for this research study.*
  Describe what action will occur in the event of pregnancy, e.g., follow-up of pregnancy outcome, immediate withdrawal from the study, *etc.*
- *Describe if there is any effect on sperm count or the motility of sperm or other reproductive risks associated with fathering a child.*
- *Describe if there are any known risks to gametes.*

Include the following information verbatim:

Risks of the usual care you receive are not risks of the research and are not included in this consent form. You should talk with your health care providers about risks of usual care.

POTENTIAL BENEFITS

This section must describe any potential benefits to the participant or to others which may reasonably be expected from the research. ***DO NOT*** *include any payment to be offered to participants for taking part. The description of benefits to the participant should be clear and not overstated in order to avoid the appearance of undue influence or coercion. If no direct benefit is anticipated, this should be stated. If research results will be given to the participant, this should be stated.*

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

Some examples on how to complete this section follow:

We can't promise that you will get any benefits from taking part in this research study. However, possible benefits may include <<list benefits>>.

OR

There are no direct benefits to you from your taking part in this research study. However, the information we get from this study may help us treat future patients.

ALTERNATIVE PROCEDURES

Describe alternative procedures or courses of treatment. To enable a rational choice about participating in the research study, individuals should be aware of the full range of options available to them, including palliative or comfort care (if applicable).

Example: You may choose not to participate in this study. If this is your decision, there are other choices such as <<list alternatives>>.

If standard therapy is part of the research study, the participant must be told he or she can receive it outside of participation in the study.

If there is no alternative treatment, state that the alternative is to not participate in the study.

You may discuss these options with your doctor.

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

CONFIDENTIALITY

Describe the procedures used to maintain the confidentiality of the records and data pertaining to the participant, how the participant's privacy will be protected, and who may inspect the records.

If you are collecting Social Security numbers, inform participants of this fact. Tell participants whether they can withhold their Social Security number and still participate.

If the research is subject to FDA regulation, a statement must be included that notes the possibility that the FDA may inspect the records.

Example: Taking part in this study will involve collecting private data about you. This data will be protected in the following ways:

- *Indicate how records are kept, e.g.,* locked in filing cabinets, on computers protected with passwords, *who will have access, etc.*
- *For large multi-site studies, discuss the number and nature of the sites and what if any information will be shared among sites>>.*

Your data will be combined with data from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

We will not share your records or identify you unless we have to by law. There are times when we may have to show your records to other people. For example, someone from the Food and Drug *Administration (if the study involves a product regulated by the FDA),* the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

VA CENTRAL IRB APPROVAL STAMP

Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

If applicable, please provide a description of the Certificate of Confidentiality and any voluntary disclosure plan, or the potential for disclosures required by law, e.g., elder abuse, child abuse, study participants posing a danger to themselves or others, etc.)

Example: We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other identifying data outside of the research study, even by a court order. Data can still be released if we find or suspect child abuse, elder abuse, an intent to harm yourself or others, or if you have an infectious disease that State or Federal law requires us to report.
The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants: *Include a statement that veteran-participants will not be required to pay for care received as a participant in a VA research study except as follows:*

You will not be charged for any treatments or procedures that are part of this study. For veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study.

If participants must bear any additional costs (e.g. transportation, time away from work, health costs, etc.) it must be disclosed in this section. Any such costs must be consistent with Federal laws concerning veterans' eligibility for medical care and treatment.

Payment Offered for Participation: *If payment is being offered for participation in the study, a separate subheading must be included with the following information. (If there is no payment being offered for participation, this should be so stated.)*

- *State whether the payment will be financial or something else such as a gift card, etc.*
- *If the payment is financial, describe the amount the participants will be paid, when payment is scheduled, how the payment will be disbursed, and the pro-rated amount the participant will receive should the participant decide to withdraw from the study or is withdrawn by the investigator.*

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Title of Study: _____

Principal Investigator:_____ Facility: _____

- *If the participant is reimbursed for certain expenses like transportation and parking, list the reimbursement rates.*

Note: VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient's medial care and when it makes no special demands on the patient beyond those of usual medial care. Any payment offered should be commensurate with the time and inconvenience of the participant incurred by the participant that they otherwise would not have incurred, as well as to cover travel expenses.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

If the study involves greater than minimal risk this section must be included and address the following:

Include this statement verbatim: Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you.

Include specific information about whom the participant should contact in case of a research-related injury. This should include name(s), telephone number(s), and when the person(s) listed may be contacted.

A number with 24-hour availability must be provided. If the number is a pager or the hospital operator include further instructions for contacting the appropriate individual.

Example: If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: *(List local site contacts)*

DURING THE DAY:

Dr./Mr./Ms. _____ at _____ and

AFTER HOURS:

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

Dr. /Mr./Ms._____ at _____.

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

VOLUNTARY PARTICIPATION

State that participation is voluntary. Indicate that refusal to take part in the study will involve no penalty or loss of benefits to which the participant is otherwise entitled. If the participant is a VA employee or student, indicate that refusal to take part in the study will in no way influence their employment, ratings, subsequent recommendations, or academic progress as applicable. Also indicate that the participant may discontinue taking part at any time without any penalty or loss of benefits. If applicable, state that the participant may withdraw and still receive the same standard of care that he or she would otherwise have received.

Example: It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are otherwise entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff and it will not affect the usual care that you receive as a patient.

Explain any possible consequences of a participant's decision to withdraw from the research. Describe any adverse effects on the participant's health or welfare, or any extra follow-up that may be requested if the participant decides to withdraw from the study. Explain the procedures for an orderly termination of participation. Such an explanation may be omitted if there are no adverse consequences to withdrawal.

Indicate that for data already collected prior to the participant's withdrawal, that the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data.. Also indicate that specimens already used cannot be withdrawn.

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

Describe foreseeable circumstances under which the participant's participation might be terminated by the investigator without regard to the participant's consent.

If the investigator might terminate participation of a participant, possible reasons should be listed and the procedures for an orderly termination of participation described. Include a description of any adverse effects on the participant's health or welfare that may result, or any additional follow-up that may be requested, if the participant is withdrawn from the study.

PERSONS TO CONTACT

Explain whom participants should contact with any questions, complaints, and concerns about the research or related matters. Contact information for the investigator should be included for questions about the research. At least one of the contacts must be someone other than the investigator or other study personnel such as the local Patient Advocate. Make sure you inform all persons listed that they are points of contact for participants and ensure they are knowledgeable concerning the study.

In addition to the above, include the following statement verbatim: If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study.

SIGNIFICANT NEW FINDINGS (Include if Applicable)

State that new findings developed during the course of the research that may affect the participant's willingness to continue participation will be provided to the participant. This section

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may be omitted if new information could not reasonably be used to alter participation (e.g., one-time interventions that are no greater than minimal risk).

Example: Sometimes during the course of a research study, new information becomes available about the <<treatment/drug>> that is being studied that could change your willingness to continue in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw at that time, your research doctor will make arrangements for your medical care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. He or she will explain the reasons and arrange for your usual medical care to continue.

PAYMENT TO INVESTIGATORS (Include if Applicable)

Describe any payments that are being made to investigators that could be construed as a potential conflict of interest. If a conflict of interest cannot be eliminated after the review by the VA Central IRB, the IRB may require that this section be included.

GENETIC RESEARCH (Include if Applicable)

- *Describe in this section possible limits to individual confidentiality based on the technologies involved in the research.*
- *If a possible commercial product will be developed as part of this research, explain that the participant will not profit from any products or tests that might result based on research with their specimens.*
- *Clarify when and under what conditions research results of genetic testing will be conveyed to the participant, the participant's family, or the participant's physician.*

Include the following statement verbatim:

A new federal law, the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

- Health insurance companies and group health plans may not request your genetic information obtained from this research.
- Health insurance companies and group health plans may not use your genetic information obtained from this research when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Reminder: Substantial sub-studies involving genetic research and analyses will require a separate consent form from the rest of the study. If this is the case, it should be so stated and reference made to the additional form.

TISSUE BANKING (Include if Applicable)

If you are planning to store blood, tissues, or specimens of any kind for future research, tissue banking guidelines must be addressed. If you plan to store these samples anywhere except VA property, please contact Biomedical Laboratory Research and Development Office at 202-254-0496.

A separate consent form will also be required for the collection of DNA for the sole purpose of adding the specimen to the CSP VA Genomic Medicine Program Biorepository.

Clarify when and under what conditions research results will be conveyed to the participant, the participant's family, or the participant's physician.

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

Explain if the participant will be re-contacted after the original project is completed. In addition to the above, specify why the tissue is being banked and the potential future uses. ***If applicable,*** *you may want to give participants a choice of how the specimen is to be used. An example of providing the participants a choice on how their specimen may be used is indicated below::*

Please read each sentence below, think about your choice, and mark "**YES**" or "**NO**". **No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.**

May the <<site>> or its research partners in this study retain your <<describe specimen (e.g., tissue, blood, urine, body fluid)>> specimen(s) after the end of the study for use in future research?

☐ **YES** **My specimen(s) may be saved for future research as follows:**

Check all restrictions that apply:

☐ **None. My specimen may be used for any future research**
☐ **Only research by the current principal investigator**
☐ **Only research that does not involve genetic testing**
☐ **Only research that involves the disease or condition to which this study pertains**

OR

☐ **None of the above. The specimen may only be used under the following conditions:**

_____

_____

VA CENTRAL IRB APPROVAL STAMP

Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

☐ **NO** **My specimen(s) must be destroyed at the end of this research study or after ____ years.**

If yes, may the <<site>> or its research partners in this study keep your name and other identifying information with your specimen(s)?

☐ **YES** **My personal identifiers and medical information can be kept with my specimen(s). All information will be kept secure and confidential.**

☐ **NO** **My name and identifiers must be removed from my specimen(s). My specimen(s) cannot be linked back to me.**

If you gave consent for the specimen(s) to be used in future research by the <<site>> or its research partners, an Institutional Review Board (IRB) will review and approve each new study. The IRB may require that you be contacted for your consent prior to the use of the specimen(s) in a new study if it decides such consent is required for your protection.

You have the right to withdraw your consent in the future and have your specimen destroyed. You need to notify the investigator of your decision. If you decide to remove identifiers from your specimen(s), you will not be able to withdraw your specimen later because it cannot be linked back to you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The following language must be included verbatim unless otherwise indicated:

Dr./Mr./Ms_____ _____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date
_____ Witness* Name	_____ Witness* Signature	_____ Date

*By signing, this individual is attesting to having witnessed the participant's signing of the consent form.

Note: If the witness is witnessing the entire consent process, this should be stated instead of the above and indicate that the witness is attesting that the participant apparently understood the information and that informed consent was freely given.

IMPORTANT: The below signature block for Legally Authorized Representatives (LAR) is only used for populations unable to provide informed consent. Only use the LAR signature block in place of the participant's signature block if it has been explained in the new study application (subject to approval by the IRB) that these types of populations are going to be used in the study). Delete this if you do not plan to enroll participants using an LAR.

The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.

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Participant Name: _____ Date:_____

Title of Study: _____

Principal Investigator:_____ Facility: _____

_____ Name of Authorized Personal Representative	_____ Signature of Authorized Personal Representative	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date
_____ Witness Name	_____ Witness Signature	_____ Date

Indicate below your authority to act as the participant's authorized personal representative:

- ☐ Spouse
- ☐ Parent
- ☐ Adult Child (18 years of age or over) for his or her parent
- ☐ Adult Sibling (18 years of age or over)
- ☐ Grandparent
- ☐ Adult Grandchild
- ☐ Guardian appointed to make medical decisions for individuals who are incapacitated
- ☐ Other per local or state law

Specify: _____

NOTE: If a local site has local policies in regard to such issues as requiring the participant's initials be on each page of the consent form, the local investigator's signature be on the consent form, noting the time the document was signed on the consent form, or any other local formatting requirement, these should be submitted as changes to the model informed consent document as part of the local site investigator application and these changes justified within the application.

VA CENTRAL IRB APPROVAL STAMP

Request for Waiver or Alteration of the Informed Consent Process

VA Central IRB
VA Institutional Review Board for Multisite Studies

This form must be included with all project applications when requesting a waiver or alteration of the informed consent process. This form cannot be used in research involving an FDA-regulated product or in research involving prisoners.

I. Project Identification

Title of Project	
Principal Investigator	

II. Type of Request

☐	Waiver of informed consent requirement for recruitment purposes only. Informed consent will be sought from participant prior to enrollment.
☐	Waiver of requirement to obtain informed consent
☐	Waiver or Alteration of one or more specific elements of the informed consent process

III. Criteria to be Eligible to Submit a Waiver or Alteration Request

The principal investigator must check that the proposed research meets one of the following criteria in order to be eligible to submit a waiver or alteration request.

☐	The research could not be practicably carried out without the waiver or alteration **and** The research is to be conducted by or subject to approval of state and local officials and is designed to study, evaluate, or otherwise examine procedures for obtaining benefits under public service programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
☐	The research meets all of the following criteria for requesting a waiver or alteration of the informed consent process: • The research involves no more than minimal tangible or intangible risk to the participants. • The waiver or alteration will not adversely affect the rights and welfare of the participants. • The research could not practicably be carried out without the waiver or alteration. • Whenever appropriate, the participants will be provided with additional pertinent information after participation.

III. Justification for Waiver or Alteration

The principal investigator must provide a response for each of the items listed below if applicable.

1. Describe why the research would not be possible without the waiver or alteration. If requesting an alteration in the informed consent process, describe how it will be altered.

2. If applicable, indicate the specific public benefit or service program, and the procedures or alternatives involved. Check ☐ if Not Applicable

3. Explain why the research for which the waiver or alteration is requested will involve no more than tangible or intangible risk.

4. Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

5. If the participants will be provided additional pertinent information after their participation, describe the additional information and how it will be provided.

IV. Investigator Certification

By signature below, the principal investigator acknowledges the following:

1. This project involves no more than minimal risk to the participant. Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2. Even if the waiver or alteration is granted, the VA Central IRB may require other conditions, such as providing the subjects with an information sheet about the research.

3. Even though a waiver or alteration may be granted, I acknowledge that it is still my responsibility to ensure that the rights and welfare of the participants are protected in accordance with VA and other federal requirements.

Signature _____ Date _____

Section V of this form is for VA Central IRB use only.

V. Review by VA Central IRB

This section is to be completed by the VA Central IRB Co-Chair based upon the actions taken at a convened meeting of the VA Central IRB or during the expedited review process.

This waiver request meets the below checked criteria for approval:

☐	The research could not be practicably carried out without the waiver or alteration **and** The research is to be conducted by or subject to approval of state and local officials and is designed to study, evaluate, or otherwise examine procedures for obtaining benefits under public service programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
☐	The research meets all of the following criteria for requesting a waiver or alteration of the informed consent process: • The research involves no more than minimal tangible or intangible risk to the participants. • The waiver or alteration will not adversely affect the rights and welfare of the participants. • The research could not practicably be carried out without the waiver or alteration. • Whenever appropriate, the participants will be provided with additional pertinent information after participation.

The action taken regarding this waiver request is indicated by the box checked below:

☐	The request for waiver of informed consent is approved for recruitment only.
☐	The request for waiver or alteration of the informed consent requirement is approved for this study as requested.
☐	The request for waiver of the informed consent requirement is approved only as indicated in the below remarks.
☐	The request for waiver or alteration of the informed consent requirement is not approved. The reasons for the disapproval are indicated in the remarks below.

Remarks:

_____

Signature of VA Central IRB Co-Chair **Date:** _____

Request for Waiver of Documentation of Informed Consent

VA Central IRB
VA Institutional Review Board for Multisite Studies

This form must be included with all project applications when requesting a waiver of documentation of informed consent. This type of waiver can be requested when using telephone, surveys, questionnaires, or when signing the informed consent form could have a negative consequence for the participant.

I. Project Identification

Title of Project	
Principal Investigator	

II. Criteria to Submit Request for Waiver of Documentation of Informed Consent

The principal investigator must check that the proposed research meets one of the following criteria:

☐ The research involves no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

or

☐ The only record linking the participant and the research would be the consent document and the principal risk to the participant would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research and the participant's wishes will govern.
NOTE: This criterion cannot be used for FDA-regulated studies.

III. Portion(s) of Research for which Investigator is Requesting Waiver

The principal investigator must check one of the boxes below. If the second box is checked, the investigator must identify the portion(s) of the study for which the requested waiver applies: (telephone survey, mailed questionnaire, etc.)

☐ This waiver request applies to all interactions with subjects detailed in the study.

☐ This waiver request applies to the following interaction(s) with subjects:

IV. Justification for Waiver

The principal investigator must provide justification that the portion(s) of the study for which waiver is requested meets waiver criteria as selected in Section II above:

V. Investigator Certification

By signature below, the principal investigator acknowledges the following:

1. Even if the waiver is granted, the VA Central IRB may require other conditions, such as providing the participants with an information sheet about the research.

2. If I checked the second box in Section II, I acknowledge that each participant must be asked whether they want documentation linking them with the research, and the participant's wish will govern.

3. Even though a waiver may be granted, I acknowledge that it is still my responsibility to ensure that the rights and welfare of the participants are protected in accordance with VA and other federal requirements.

_____ _____

Signature Date

Section VI is for VA Central IRB use only.

VI. Review by VA Central IRB

This section is to be completed by the VA Central IRB Co-Chair based upon the actions taken at a convened meeting of the VA Central IRB or during the expedited review process.

This waiver request meets the below checked criteria for approval:

☐ The research involves no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

or

☐ The only record linking the participant and the research would be the consent document and the principal risk to the participant would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research and the participant's wishes will govern.

The action taken regarding this waiver request is indicated by the box checked below:

☐	The request for waiver or documentation of informed consent requirement is approved for this study as requested.
☐	The request for waiver of the documentation of informed consent is approved only as indicated in the below remarks.
☐	The request for waiver of documentation of informed consent is not approved. The reasons for the disapproval are indicated in the remarks below.

Remarks:

_____

Signature of VA Central IRB Co-Chair **Date:** _____